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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,442	07/24/2001	Samir S. Mitragotri	031852.0029	1231

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/868,442	MITRAGOTRI ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72,74-110,112 and 114-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *77-79,89,93,94 and 100* is/are allowed.

6)☒ Claim(s) *72,74-76,82,83,86-88,90,95-97,99-101,103-110,112 and 114-119* is/are rejected.

7)☒ Claim(s) *80,81,84,85,91,92,98 and 102* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 72, 74, 82, 88, 90, 99, 101, 107, 108, 112, 114 and 117 - 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,587,705 to Kim et al. in view of U.S. Patent No. 4,767,402 to Kost et al.

In reference to claims 72, 74, 82, 88, 90 and 101, Kim et al. discloses applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5); extracting at least one analyte from the area of skin by application of a transport force (Col. 10, lines 47 – 53); receiving the analyte in a sensing zone in communication with the area (Col. 10, lines 51 – 52); and monitoring changes in the analyte concentration of the body fluid by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). Kim et al. discloses the transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces (Col. 10, lines 47 – 53), cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. The transport force is an ultrasound force and is applied to create a result selected from pumping body fluid and fluid components, activating gas bodies, producing cyclic impulse mechanical stress, create microstreaming, increase

temperature and set up standing waves (Col. 10, lines 47 – 53). Receiving the at least one analyte comprises using a method from the group of absorption, adsorption, phase separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof (Col. 10, lines 47 – 53). The determining step includes a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 10, line 53 – Col. 11, line 40). Kim et al discloses increasing a permeability level of an area of skin with low frequency ultrasound forces as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency as disclosed by Kim et al. to be less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8).

In regards to claims 107, 108, 112 and 114, Kim et al. discloses applicant's claimed invention including a low frequency ultrasonic transducer (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5); means providing an extraction transport force (Col. 10, lines 47 – 53); a sensing zone; and a sensing device in the sensing zone for monitoring changes in the analyte concentration of the body fluid by continuously measuring the quantity of at least one analyte (Col. 10, lines 15 – 23). Kim et al. discloses means providing an extraction transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces (Col. 10, lines 47 – 53), cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. The sensing device senses the presence of at least one

analyte by applying a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 10, line 53 – Col. 11, line 40). Kim et al discloses a low frequency ultrasound transducer which operates as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency transducer as disclosed by Kim et al. to operate less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8).

In regards to claims 99, 117 – 119, Kim et al. discloses a system and method for blood glucose determination including a low frequency ultrasound transducer for increasing the permeability of the skin (Col. 10, lines 28 – 31; Col. 7, lines 4 – 5) an extraction device for extracting glucose from the skin (Col. 10, lines 47 – 53); a receiving device for receiving the glucose; a hydrophilic gel in the receiving device; at least one glucose sensitive reagent that changes a characteristic of the gel (Col. 10, line 53 – Col. 11, line 40); and a monitoring device for monitoring changes in the glucose concentration of the blood by continuously monitoring (Col. 10, lines 15 – 23) the change in the characteristic of the gel. Kim et al discloses increasing a permeability level of an area of skin with low frequency ultrasound forces as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound

frequency as disclosed by Kim et al. to be less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8).

3. Claims 72, 74 – 76, 82, 83, 90, 97, 101, 107, 112 and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. in view of U.S. Patent No. 6,587,705 to Kim et al. and further in view of U.S. Patent No. 4,767,402 to Kost et al.

In reference to claims 72, 74 – 76, 82, 83, 90, 97 and 101, Shain et al. discloses applicant's claimed invention including increasing a permeability level of an area of skin with low frequency ultrasound (Col. 2, lines 64 - 67); extracting at least one analyte from the area of skin (Col. 4, line 49); receiving the analyte in a sensing zone (18) in communication with the area; and determining the quantity of the analyte in the sensing zone (Col. 3, lines 14 – 24). Shain et al. discloses extracting a body fluid being selected from physical forces, chemical forces, vacuum (Col. 3, lines 33 – 35), electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic forces, magnetic forces, photo acoustic forces and any combination thereof. The ultrasound is applied to create a result selected from pumping body fluid and fluid components, activating gas bodies, producing cyclic impulse mechanical stress, create microstreaming, increase temperature and set up standing waves (Col. 3, lines 60 - 64). Collecting the at least one analyte comprises using a method from the group of absorption, adsorption, phase separation, mechanical, electrical, chemically induced, capillary forces and a combination thereof (Col. 3, lines 50 – 53). The mechanical collection method comprises applying vacuum, pressure or acoustic forces. The determining step includes a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 3, lines 17 - 20). Shain et al. discloses that the determining of the quantity of the analyte can be performed with any method

or sensor (Col. 3, lines 16 – 20). However, Shain fails to disclose monitoring changes in the analyte concentration by continuously determining the quantity of the analyte. Kim et al. discloses a method for analysis of at least one analyte in a body fluid wherein the sensor is used to monitor changes in the analyte concentration by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. to utilize a sensor and method as taught by Kim et al. to monitor changes in the analyte concentration by continuously determining the quantity of the analyte in the sensing zone in order to monitor concentration swings of the analyte (Col. 3, lines 1 – 5). Kim et al discloses increasing a permeability level of an area of skin with low frequency ultrasound forces as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency as disclosed by Shain in view of Kim et al. to be less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8).

In regards to claims 107, 112 and 114, Shain et al. discloses applicant's claimed invention including a low frequency ultrasonic transducer (Col. 2, lines 64 - 67); means providing an extraction transport force (14); a sensing zone (18); and a sensing device in the sensing zone for measuring the quantity of at least one analyte (Col. 3, lines 14 – 24). Shain et al. discloses means providing an extraction transport force being selected from physical forces, chemical forces, vacuum, electrical forces, osmotic forces, diffusion forces, electro-magnetic forces, ultrasound forces, cavitation forces, mechanical forces, thermal forces, capillary forces, fluid circulation across the skin, electro-acoustic

forces, magnetic forces, photo acoustic forces and any combination thereof (Col. 2, line 67 – Col. 3, line 2). The sensing device senses the presence of at least one analyte by applying a sensing method selected from the group of electrochemical, optical, acoustical, biological, enzymatic technology and combinations thereof (Col. 3, lines 17 –24). Shain et al. discloses that the determining of the quantity of the analyte can be performed with any method or sensor (Col. 3, lines 16 – 20). However, Shain fails to disclose the sensing device in the sensing zone monitoring changes in the analyte concentration by continuously determining the quantity of the analyte. Kim et al. discloses a method for analysis of at least one analyte in a body fluid wherein the sensing device is used to monitor changes in the analyte concentration by continuously determining the quantity of the analyte in the sensing zone (Col. 10, lines 15 – 23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensing device as disclosed by Shain et al. to monitor changes in the analyte concentration by continuously determining the quantity of the analyte in the sensing zone as taught by Kim et al. in order to monitor concentration swings of the analyte (Col. 3, lines 1 – 5). Kim et al discloses a low frequency ultrasound transducer which operates as low as 10 MHz, and states that lower frequencies may be used (Col. 17, lines 41 – 47). However, Kim et al. fails to disclose the frequency being less than 2.5 MHz. Kost et al. teaches the use of low frequency ultrasound forces less than 2.5 MHz to increase the permeability of skin (Col. 3, lines 26 – 29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the low level ultrasound frequency transducer as disclosed by Shain in view of Kim et al. to operate less than 2.5 MHz as taught by Kost et al. so as to avoid any significant temperature rise and destructive effect on skin (Col. 8, lines 5 – 8).

4. Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. in view of U.S. Patent No. 6,587,705 to Kim et al. and further in view

of U.S. Patent No. 4,767,402 to Kost et al. as applied to claim 74 above, and still further in view of U.S. Patent No. 6,468,229 to Grace et al.

In reference to claims 86 and 87, Shain et al. in view of Kim et al. and Kost et al. discloses using a mechanical force to enhance the physical movement of liquid across the skin (Col. 3, lines 50 – 53), but fails to disclose using a tensioner having a cavity to collect the fluid therein. Grace et al. discloses a tensioner (Figures 2A – G) having a cavity (26) for the collection of fluid. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. in view of Kim et al. and Kost et al. to include the steps of using a tensioner having a cavity to collect fluid therein as taught by Grace et al. in order to increase the amounts of interstitial fluids that are collected (Col. 2, lines 25 – 30).

5. Claims 95 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. in view of U.S. Patent No. 6,587,705 to Kim et al. and further in view of U.S. Patent No. 4,767,402 to Kost et al. as applied to claim 90 above, and still further in view of U.S. Patent No. 6,503,198 to Aronowitz et al.

In reference to claims 95 and 96, Shain et al. in view of Kim et al. and Kost et al. fails to disclose a hydrophobic coating being applied to the skin prior to extracting a body fluid from the skin. Aronowitz et al. teaches applying a hydrophobic coating to the skin prior to fluid extraction from the skin (Col. 16, lines 16 – 46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. in view of Kim et al. and Kost et al. to include the step of applying a hydrophobic coating to the skin prior to fluid extraction as taught by Aronowitz et al. in order to enhance the permeation of the skin (Col. 16, lines 38 – 44).

6. Claims 103 – 106, 109, 110, 115 and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,009,343 to Shain et al. in view of U.S. Patent No. 6,587,705 to Kim et al. and further in view of U.S. Patent No. 4,767,402 to Kost et al. as applied to claims 72 and 107 above, and further in view of U.S. Patent No. 5,722,397 to Eppstein.

In regards to claims 103 – 106, 109, 110, 115 and 116, Shain et al. in view of Kim et al. and Kost et al. fails to disclose providing an output controlled by a microcontroller for a user interface having an alarm that indicates an abnormal analyte concentration and trend information that is downloadable. However, Eppstein discloses a method for analysis of at least one analyte in body fluid including providing an output for a user interface having an alarm that indicates an abnormal analyte concentration (Col. 21, lines 10 – 18) and trend information that is downloadable (Col. 19, lines 7 – 13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Shain et al. in view of Kim et al. and Kost et al. to provide an output as taught by Eppstein in order to indicate to the user or diagnostician the need for administration of appropriate medication if necessary (Col. 21, lines 10 – 13).

Allowable Subject Matter

7. Claims 77 – 79, 89, 93, 94 and 100 are allowed. Claims 80, 81, 84, 85, 91, 92, 98 and 102 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMLF